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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,662	12/27/2001	Eugene Herman	9195-081-999	7952

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,662	HERMAN ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1-7 (in part), drawn to methods of screening or identifying a subject at risk of developing Cardiac Response, classified in class 435, subclass 6, for example.
 2. Claims 1-7 (in part), drawn to methods of monitoring the effects of therapy administered in a subject, classified in class 435, subclass 4, for example.
 3. Claims 8-12 and 45-47 (in part), drawn to drawn to methods of screening or identifying a subject at risk of developing Cardiac Response using proteins, classified in class 435, subclass 7.1, for example.
 4. Claims 8-12 and 45-47 (in part), drawn to methods of monitoring the effects of therapy administered in a subject using proteins, classified in class 435, subclass 4, for example.
 5. Claims 13-17, drawn to proteins and kits comprising said proteins, classified in class 530, subclass 350, for example.
 6. Claims 18-24, drawn to antibodies and kits comprising said antibodies, classified in class 530, subclass 387.1, for example.
 7. Claims 25-27, drawn to drawn to methods of treating Cardiac Response using a nucleic acid, classified in class 514, subclass 44, for example.
 8. Claims 28-30, 41 and 43-44, drawn to methods of screening for agents that interact with a polypeptide, classification undeterminable; classification dependent on agent.

9. Claims 31-40, 42-44, 48 and 53, drawn to methods of screening agents that modulate expression or activity of a VRPI, classified in class 435, subclass 4, for example.
10. Claims 49-51, drawn to an agent that modulates activity, classification undeterminable; classification dependent on agent.
11. Claim 52, drawn to a method of treating or preventing comprising administering an agent that modulates activity, classified in classification undeterminable; classification dependent on agent.

Further Restriction

The claims of Groups 1-11 are drawn to a multitude of Cardiac Response Associated Features, Cardiac Response Associated Protein Isoforms, antibodies thereto and methods which use these compounds. Each of the different Cardiac Response Associated Features, Cardiac Response Associated Protein Isoforms, antibodies and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups 1-11, Applicant is additionally required to elect a **single** Cardiac Response Associated Feature, Cardiac Response Associated Protein Isoform, or antibody. For example, Applicants could elect Group 1, and CRF-1, or Group 7 and CRPI-1. This requirement is not to be construed as a requirement for an election of species, since each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

2. The inventions are distinct, each from the other because of the following reasons:

A) Inventions 1-4, 7-9 and 11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to methods having different method steps, starting materials, and goals. For example, Inventions 1 and 2 are unrelated because Invention 1 is drawn to methods of *screening or identifying a subject at risk of developing Cardiac Response*, whereas Invention 2 is drawn to methods of *monitoring the effects of therapy administered in a subject*, whereas Invention 3 is drawn to methods of screening or identifying a subject at risk of developing Cardiac Response *using proteins*, etc.

B) The inventions of Groups 5, 6 and 10 are patentably distinct because they are drawn to different products having different structures and functions. The polypeptide of Group 5 is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group 6 is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e., epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Contrarily, the agent of Group 10 does not have a specified structure. Furthermore, the products of Groups 5, 6 and 10 can be used in materially different processes, for example, the antibody of Group 6 can be used in an immunoassay, the polypeptide of Group 5 can be used to

make fusion proteins with an enzymatic function, whereas the agent of Group 10 can be used in making a medicament for the treatment or prevention of Cardiac Response. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups 5, 6 and 12 are patentably distinct from each other. (See MPEP § 806.04, MPEP § 808.01, unrelated inventions)

C) Inventions 5 and 1, 3 and 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the proteins of Group 5 are not required for the methods of Groups 1, 3, 8 and 9. As such, the Inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

D) Inventions 5 and 2, 4, 8, 9 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Group 5 could be used in any of the methods of 2, 4, 7, 10-11 and 13, or in an entirely different manner, such as in a purification reaction or in making antibodies.

E) Inventions 6 and 1-4, 7-9 and 11 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are not required one for the other in that the antibodies of Group 6 are not required for the methods of Groups 1-4, 7-9 and 11. As such, the Inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

F) Inventions 10 and (1-4 and 7-9) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the agents of Group 12 are not required for the methods of Groups 1-4 and 7-9. As such, the Inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

H) Inventions 10 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agents of Group 10 could be used the methods of Group 11, or in an entirely different manner, such as in a method of modulating activity.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions 1-11 require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

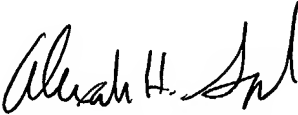
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Alexander H. Spiegler
September 21, 2003


CARLA J. MYERS
PRIMARY EXAMINER